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| 10/708,723 | 03/19/2004 | Ehud J. Schmidt | GEMS8081.204 | 2722 |
| 27061 | 7590 | 10/29/2010 | EXAMINER | |
| ZIOLKOWSKI PATENT SOLUTIONS GROUP, SC (GEMS) 136 S WISCONSIN ST PORT WASHINGTON, WI 53074 | | | WEATHERBY, ELLSWORTH | |
| ART UNIT | | PAPER NUMBER | | |
| | | 3768 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/708,723 | SCHMIDT, EHUD J. |
| | Examiner | Art Unit |
| | ELLSWORTH WEATHERBY | 3768 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 September 2010.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-17, 19-28 and 30-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-17, 19-28 and 30-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1 and 4-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. (USPN 6,628,980) in view of Karmarkar et al. (Pub. No.: 2004/0046557).

3. **Regarding claims 1, 4 and 16**, Atalar et al. (hereinafter Atalar) teaches a probe for acquiring data in a magnetic resonance imaging (Abstract; Figs. 1-18), comprising: A self expanding distal head insertable into a subject's vascular system to be imaged and constructed to permit fluid or blood flow therethrough (col. 3, lines 55-67; col. 4, lines 1-5; col. 14, ll. 30-65; col. 19, lines 50-56 See also Distal head of Figure 6D). Here, the distal region comprises an imaging coil (644), comprising a plurality of RF coils (607a, 607b) that are expandable when tubular member (698) is retracted. For example, Atalar teaches a multi coil MRI probe comprising an expandable probe (870) that is advanced so that the RF coil (804) protrudes from the sleeve (868) (col. 16, ll. 29-37). In the expanded state, the coil (804) forms a gap between the coil (804) and the nested expandable probe (870). Another embodiment that reads on the present claim 1 is

described by Figures 8A-B or 9A-B. Here, a loop imaging coil (972) is inserted into a loopless imaging coil sleeve (974) (col. 16, l. 50-col 17, l. 24). Furthermore, the gap between the housing and the coil (804) is configured to increase RF sensitivity away from the probe (col. 16, l. 64- col. 17, l. 24). Also, the MRI sleeve and probe may comprise one or more imaging coils (col. 16, ll. 59-63; col. 17, ll. 19-24). Therein, Atalar teaches that the combination provides a sensitivity profile combining the strengths of both types of coils is achieved.

4. **Regarding claims 6-9**, Atalar also teaches a shaft connected to the housing and constructed to position the housing within the subject to be imaged (col. 4, lines 40-43). Atalar et al. '980 also teaches a retractable sheath constructed to enclose the housing during insertion into the subject and translation to a target tissue to be imaged and further constructed to be retracted by a user to allow the housing to expand when proximity to the target tissue is reached (col. 16, lines 29-31). Atalar et al. '980 also teaches that the sheath is constructed to enclose the housing during insertion into the subject and translation to a target tissue to be imaged and further constructed to be retracted by a user to allow the housing to expand when proximity to the target tissue is reached (col. 15, lines 66-67; col. 16, 1-11; col. 16, lines 29-31). Atalar et al. '980 also teaches that the sheath is formed of a material that applies a compression force upon the housing and the plurality RF coils during insertion into the subject and translation to the target tissue to be imaged, and wherein the housing is constructed of material to automatically expand the plurality RF coils when the compression force is removed, and

further, that the sheath has a shaft that exceeds a distance from an insertion point to the target tissue to be imaged (col. 15, lines 66-67; col. 16, 1-37).

5. **Regarding claims 10-14,** Atalar teaches that the housing comprises a first pair of bars and a second pair of bars in first and second orthogonal planes forming the first and second RF loop coils, comprising a nitinol and insulating material (col. 14, ll. 30-67; refs. 607A-B).

6. Atalar discloses as well known that loop imaging coils provide near field imaging with increased sensitivity distributed across their length (col. 17, ll. 1-15). It is within reason that one of ordinary skill in the art would interpret the gap formed between the plurality of expanded RF coils and the housing to be met by the expanded loop coils of Atalar. However, if it is interpreted that Atalar does not expressly teach that the RF coils attachment means to the housing forms a gap, there is nothing in the disclosure to show why the multiple expandable coils of Atalar is not an obvious variant of the present application's gap formed between the RF coils and housing, because both Atalar and the present invention are concerned with achieving the same function of increasing RF sensitivity away from the probe. Furthermore, Atalar anticipates each and every other limitation and even obviates the claimed attachment limitation, e.g. incorporating by reference USPN 5,699,801, USPN 5,928,145 and USPN 5,928,145 as alternative coil designs for use within the expandable device (col. 9, ll. 22-29; col. 12, ll. 43-64; col. 13, ll. 15-27). Quoting Atalar, "The detector coil (504) may comprise a loopless imaging coil or a loop imaging coil of any type known in the art, including those types described above and by Ocali et al. in U.S. Pat. No. 5,928,145, by Atalar '801, and by Atalar

'229.". As an example of the obviousness of attaching RF coils to expandable members similar to those of Atalar, the Examiner sets forth the following reference.

7. In the same field of endeavor, Karmarker et al. teaches an intra-cardiac magnetic resonance probe (Abstract; Figs. 1-10C). Karmarker goes on teaching an expandable basket similar to that disclosed by Atalar (Figs. 6A-D). Here, Karmarker teaches that each expandable arm comprises a plurality of electrodes (0069). Karmarker goes on, further teaching that the electrodes disposed on the arm may be glued or bonded (0070). Here, the examiner stands that a gap is inherently formed between the coils and the housing, the gap comprising the glue or bon material). Karmarker further teaches that miniature loop coils may be placed adjacent to the one or more electrodes attached to the radially expandable housing (0070).

8. The Examiner stands that it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the expandable housing comprising imaging coils of Atalar in view of the attachment means for an RF coil to an expandable housing of Karmarker. The motivation to modify Atalar in view of Karmarker would to utilize any known RF coil or attachment means to improve imaging quality in the radial direction.

9. **Claims 2-3** are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. (USPN 6,628,980) in view of Karmarker et al. (Pub. No.: 2004/0046557) as applied to claim 1 above, and further in view of Nevo et al. (USPN 6,516,213).

10. The expandable imaging device of Atalar in view Karmarkar teaches all the limitations of the claimed invention except for expressly teaching that a tracking coil is configured to transmit tracking signals for gating data acquisition.

11. In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils, which are configured to transmit tracking signals for gating data acquisition (col. 14, ll. 21-40; col. 15, ll. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, l. 55- col. 14, l. 18).

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the expandable RF probe of Atalar in view of Karmarkar with the tracking coils for gating acquisition of Nevo. The motivation to modify Atalar in view of Karmarkar with Nevo would have been to provide accurate readings of position or orientation of an intra-cardiac probe throughout the procedure where the position data is acquired using known tracking coils, as taught by Nevo.

13. **Claims 26-28 and 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Atalar et al. (USPN 6,628,980) in view of Karmarkar et al. (Pub. No.: 2004/0046557) and Nevo et al. (USPN 6,516,213).

14. The expandable imaging device of Atalar in view Karmarkar teaches all the limitations of the claimed invention, as noted above. However, Atalar in view of Karmarkar does not expressly teach that a tracking coil is configured to transmit

tracking signals for gating data acquisition. Atalar in view of Karmarkar also does not expressly teach that the device is an intra-cardiac device.

15. In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils, which are configured to transmit tracking signals for gating data acquisition (col. 14, ll. 21-40; col. 15, ll. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, l. 55- col. 14, l. 18). Here, the Examine that the combination of Atalar in view of Karmarkar and Nevo provides instantaneous tracking the device at any time, including prior to retracting the sheath (See Nevo: Abstract).

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the expandable RF probe of Atalar in view of Karmarkar with the tracking coils for gating acquisition of Nevo. The motivation to modify Atalar in view of Karmarkar with Nevo would have been to provide accurate readings of position or orientation of an intra-cardiac probe throughout the procedure where the position data is acquired using known tracking coils, as taught by Nevo.

17. **Claims 17 and 19-21 and 23-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (USPN 6,292,683) in view of Atalar et al. (USPN 6,628,980) and Nevo et al. (USPN 6,516,213).

18. Gupta et al. (hereinafter Gupta) teaches an MRI apparatus (Abstract: Figures 1-4), comprising: a magnetic resonance imaging (MRI) system having a plurality of

gradient coils positioned about bore of a magnet to impress a polarizing magnetic field and an RF transceiver system and an RF switch controlled by a pulse module to transmit RF signals to an RF coil assembly to acquire MR images (col. 3, ll. 42-65), the RF assembly being used to track the motion of a medical instrument (col. 3, ll. 26-41).

19. Gupta does not expressly teach that the RF coil assembly comprises an intra-cardiac catheter configured for insertion into a blood flow and constructed to automatically expanded position from a compressed position; a plurality of RF coils connected to the catheter and configured to acquire MR data; a tracking coil connected to the catheter and configured to acquire MR data; a tracking coil connected to the catheter and configured to indicate RF coil assembly location and movement within an imaging subject; wherein the tracking coil is configured to transmit signal indicating the location and movement of the RF coil assembly to the MRI system to facilitate MR data acquisition gating; and wherein the MRI system is configured to gate MR data acquisition during imaging based on the location and movement of the RF coil assembly.

20. In a related field of endeavor, Atalar et al. (hereinafter Atalar) teaches a probe for acquiring data in a magnetic resonance imaging (Abstract; Figs. 1-18), comprising: A self expanding distal head insertable into a subject's vascular system to be imaged and constructed to permit fluid or blood flow therethrough (col. 3, lines 55-67; col. 4, lines 1-5; col. 14, ll. 30-65; col. 19, lines 50-56 See also Distal head of Figure 6D). Here, the distal region comprises an imaging coil (644), comprising a plurality of RF coils (607a, 607b) that are expandable when tubular member (698) is retracted (In this regard the

RF coils are connected to the catheter and configured to acquire MR data). For example, Atalar teaches a multi coil MRI probe comprising an expandable probe (870) that is advanced so that the RF coil (804) protrudes from the sleeve (868) (col. 16, II. 29-37). Atalar further teaches that the expanded diameter substantially matches an inner diameter of a target tissue in which the probe is placed (claim 49). Atalar teaches that the housing comprises a first pair of bars and a second pair of bars in first and second orthogonal planes forming the first and second RF loop coils, comprising a high memory nitinol and insulating material (col. 14, II. 30-67refs. 607A-B: Here, the Examiner notes that the upon retraction of the sheath the plurality of RF coils are configured to automatically expand from a compressed position).

21. Atalar does not expressly teach that the catheter is an intra-cardiac catheter or that the tracking coil is configured to transmit tracking signals for gating data acquisition.

22. In the same field of endeavor, Nevo et al. (hereinafter Nevo) teaches a method and apparatus to estimate location and orientation of object during MRI (Abstract; Figs. 1-7). Nevo goes on teaching using tracking coils configured to transmit tracking signals for gating data acquisition (col. 14, II. 21-40; col. 15, II. 8-55). Nevo also teaches utilizing the system for tracking catheters in intra-cardiac procedures (col. 13, I. 55- col. 14, I. 18).

23. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the MRI system for tracking medical devices of Gupta in view of the expandable RF probe of Atalar and the tracking coil for gating acquisition of Nevo. The

motivation to modify Gupta in view of Atalar and Nevo would have been to provide dynamic intra-cardiac imaging using known devices or techniques.

24. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (USPN 6,292,683) in view of Atalar et al. (USPN 6,628,980) and Nevo et al. (USPN 6,516,213) as applied to claim 21 above, and further in view of Karmarkar et al. (Pub. No.: 2004/0046557).

25. Gupta et al. (USPN 6,292,683) in view of Atalar et al. (USPN 6,628,980) and Nevo et al. (USPN 6,516,213) teach all the limitations of the claimed invention. However, Applicant contests the obviousness of the claimed RF coil attachment to the bars that was set forth in the 1/26/2010 Non-Final Rejection. However, as noted above, Atalar discloses as well known that loop imaging coils provide near field imaging with increased sensitivity distributed across their length (col. 17, ll. 1-15). If it is interpreted that Atalar does not expressly teach that the claimed RF coils attachment means to the housing, there is nothing in the disclosure to show why the multiple expandable coils of Atalar is not an obvious variant of the present application's RF coils attached to first and second set of bars, because both Atalar and the present invention are concerned with achieving the same function of increasing RF sensitivity away from the probe. Furthermore, because Atalar so clearly anticipates each and every other limitation and even obviates the claimed attachment limitation, e.g. incorporating by reference USPN 5,699,801, USPN 5,928,145 and USPN 5,928,145 as alternative coil designs for use within the expandable device (col. 9, ll. 22-29; col. 12, ll. 43-64; col. 13, ll. 15-27), the

Examiner had taken the position that the disclosure of Atalar obviates the presently claimed invention. Quoting Atalar, "The detector coil (504) may comprise a loopless imaging coil or a loop imaging coil of any type known in the art, including those types described above and by Ocali et al. in U.S. Pat. No. 5,928,145, by Atalar '801, and by Atalar '229.". As an example of the obviousness of attaching RF coils to expandable members, the examiner sets forth the following reference.

26. In the same field of endeavor, Karmarker teaches an intra-cardiac magnetic resonance probe (Abstract; Figs. 1-10C). Karmarker goes on teaching an expandable basket similar to that disclosed by Atalar (Figs. 6A-D). Here, Karmarker teaches that each expandable arm comprises a plurality of electrodes (0069). Karmarker goes on, further teaching that the electrodes disposed on the arm may be glued or bonded (0070). Karmarker further teaches that miniature loop coils may be placed adjacent to the one or more electrodes attached to the radially expandable housing (0070).

27. As noted above, Atalar was set forth as obviating the claimed first set of bars attached to the first RF coil and second set of bars attached to the second coil. However, Applicant contests that obviousness. The Examiner stands that because Atalar suggests using a plurality of detector coil designs, e.g. incorporating by reference USPN 5,699,801, USPN 5,928,145 and USPN 5,928,145, and noting that the detector coil may comprise a loopless imaging coil or a loop imaging coil of any type known in the art, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the expandable housing comprising imaging coils of Atalar in view of the attachment means for an RF coil to an expandable housing of Karmarker .

The motivation to modify Atalar in view of Karmarkar would to utilize any known RF coil or attachment means to improve imaging quality in the radial direction.

Response to Arguments

28. Applicant's arguments, filed 09/13/2010, with respect to the finality 07/12/2010 Final Rejection have been fully considered and are persuasive. Therefore, the Finality of the 07/12/2010 rejection has been withdrawn.

29. Applicant alleges in the 09/13/2010 Response that the claims call for a self-expanding housing insertable into a subject to be imaged and constructed to permit fluid flow therethrough, a plurality of RF coils attached to the housing and wherein a gap formed between the plurality of RF coils and the housing is configured to increase RF sensitivity away from the probe. Specifically applicant alleges that Atalar does not teach that the coils are attached to a self-expanding housing. Here, the Examiner notes that the position of the office is that Atalar teaches a self expanding housing comprising coils, as noted above. However, the Examiner stands that Karmarker remedies any deficiencies of Atalar by teaching as known positioning RF coils on an expandable housing using gluing or bonding techniques.

28. In KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art,"*Id.* at ___, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based

on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”*Id.* at ___, 82 USPQ2d at 1395. The Supreme Court stated that there are “[t]hree cases decided after Graham [that] illustrate this doctrine.” *Id.* at ___, 82 USPQ2d at 1395. (1) “In *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *Id.* at ___, 82 USPQ2d at 1395. (2) “In *Anderson ’s-Black Rock, Inc. v. Pavement Salvage Co.*, . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation.” *Id.* at ___, 82 USPQ2d at 1395. (3) “[I]n *Sakraida v. AG Pro, Inc.*, the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at ___, 82 USPQ2d at 1395-96 (Internal quotations omitted.). The principles underlining these cases are instructive when the question is whether a patent application claiming the combination of elements of prior art would have been obvious. The Supreme Court further stated that: When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way,

using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at ___, 82 USPQ2d at 1396.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768